

**REMARKS**

This application is amended in a manner to place it in condition for allowance at the time of the next Official Action.

**Status of the Claims**

Claims 44-63 are new and correspond to claims 24-43, respectively, and are substantially amended as to form to render the claims as definite.

Claims 44 and 62 additionally recite that the at least one sterol and/or ester is without thickener and without emulsifier. Basis for this recitation may be found in page 2, line 15-18 of the specification, i.e., "The purpose of the present invention is therefore to provide a preparation methd..., without thickener and without emulsifier,...".

Claim 55 has been substantively amended to require a smoothing step and a cereal addition step.

Claims 24-43 have been canceled.

No new matter has been added.

**Objection to the Specification**

The specification was objected to for not providing the appropriate section headings. These section headings, along with a Brief Description of the Drawings has been added per the "AMENDMENT TO THE SPECIFICATION" section of this response.

No new matter has been added.

Therefore, withdrawal of the objection is respectfully requested.

**Claim Rejections-35 USC §112**

Claims 25-43 were rejected under 35 U.S.C. §112, second paragraph, for being indefinite. This rejection is respectfully traversed for the reasons below.

New claims 44 to 63 correspond to claims 24 to 43, respectively and utilize active voice.

The difference between "preheating temperature" and "heating temperature" are now clearly defined. That is, preheating involves treatment of the milk-based initial composition, whereas heating involves the dairy composition. See, for example page 3, lines 3-6 for a description of the milk-based initial composition and dairy composition.

Several of the claims 50-54 and 56 were rejection for including an optional step. These steps are not required.

Each claim recites only a single range per variable.

Claim 58 is limited to one agent, and does not recite a preferred or particular agent.

Claim 59, similar to the other dependent claims, refers to the "at least one sterol and/or stanol ester" as simply "said ester" to avoid confusion.

Therefore, the claims are definite, and withdrawal of the rejection is respectfully requested.

**Claim Rejections-35 USC §103**

Claims 24-43 were rejected under 35 U.S.C. §103(a) as being unpatentable over DOAT U.S. 6,627,245 (DOAT) in view of BOYER EP 1212945 (BOYER). This rejection is respectfully traversed for the reasons below.

The objective of the claimed invention.

The claimed invention concerns a method for the preparation in a production line of a dairy product comprising a introducing by continuous injection, via the production line, of at least one sterol and/or stanol ester (without either a thickener or an emulsifier) at a given temperature  $T_1$  higher than or equal to the melting temperature of the ester, and ranging from 35 to 80°C, dairy composition having a given temperature  $T_2$  at least equal to  $T_1$  corresponding to a milk-based initial composition, containing milk proteins and without emulsifier, in order to obtain a mixture. The introduction of the ester is carried out before the mixture is homogenized.

In the prior art, the incorporation of a sterol and/or stanol ester into a milk composition required (i) a batch process and (ii) a stabilizer, essentially a thickener, and with an emulsifier.

Therefore, one of the advantages of the claimed invention is the ability to incorporate a sterol and/or a stanol

ester into a milk composition without using a batch process but in a continuous injection.

Another advantage of the claimed invention lies in the fact that the incorporation of the sterol and/or stanol ester is carried out without emulsifier.

#### DOAT

DOAT relates to a stable homogeneous emulsifier-free suspension, of at least one hydrophobic substance and/or a substance where the melting point is higher than about 130°C, and a thickening agent, in an aqueous medium. This suspension can be used in food compositions, in particular those based on milk and milk derivatives.

#### BOYER

BOYER discloses a process of incorporating cholesterol-lowering agents into dairy-based beverages.

In particular, a melted stanol ester at a temperature of 60°C is incorporated into a milk stabilizer mixture heated at a temperature of 62.8°C. The resultant mixture is then blended in a mixer, and homogenized at a pressure of 137-172 bars and pasteurized at a temperature of 87.8°C for 2 minutes.

The Combination of DOAT and BOYER

The process of DOAT requires a thickener in the suspension comprising the hydrophobic substance (see claim 1), while in the independent claim 44 of the present invention, no thickener is present with sterol and/or stanol ester.

Therefore, the method of the presently claimed invention is different from the method used by DOAT.

The process of BOYER is only intended for fresh dairy products. BOYER describes only one dairy-based beverage, which is prepared in a batch process and the composition requires a stabilizer such as carrageenan (as in page 5 line 25-30 or Example 1) and an emulsifier (see table 1).

Therefore, the two main differences between the process of BOYER and the claimed invention are:

a) The need for a stabilizer.

BOYER does not disclose a process carried out without using a stabilizer and emulsifier, wherein the temperature  $T_1$  of the stanol and/or sterol ester must be higher than or equal to the melting temperature of the ester and wherein said ester is introduced into a milk composition the temperature  $T_2$  of which is at least higher than  $T_1$ .

Indeed, a stabilizer is essential and must be used according to BOYER for the very same ester as claimed. As stated in page 3, line 12-13 of BOYER: "Additionally, it may be possible

*to eliminate the need for stabilizers by substituting stanol with other selected fatty acids for a stabilizing agent."* (Emphasis added)

In other words, according to BOYER a stable dairy product is obtained by either using a stabilizer such as carrageenan or a stabilizing agent in place of the stanol, e.g., such as another fatty acid.

This is also discussed in the present specification. A "stabilizer" is referred to as "thickener" in the specification, see page 2 line 6-9: *"The document EP 1 212 945 relates to a dairy-based beverage comprising a stanol ester at a rate of 0.2 to 2% by weight which can contain a thickener, among other ingredients. All the applications cited mention the use of stabilizers, essentially thickeners and sometimes emulsifiers."* (Emphasis added)

Thus, in order to even approach the claimed invention in terms of composition would have been contrary to the teachings of BOYER.

Even if one ignored these teachings, one would have been discouraged from looking to BOYER for guidance.

For example, it is well known that carrageenan is not compatible with fermented dairy product process. Indeed, carrageenan and other polymers cause a flocculation of proteins in acidic medium.

Moreover, the quality of a dairy product is determined by its texture, and it will be appreciated by the consumer only by its proteic array. The use of carrageenan does not allow the structuring of such an array and therefore does not lead to a product with acceptable qualities.

b) The need for a batch process.

The process of BOYER is a batch process, i.e., all of the compounds are put in a reactor, and they are then mixed, while in the claimed invention, the sterol is incorporated in a continuous manner. That is, the sterol or stanol is present in a line different from the one of the milk line, and both lines are then mixed continuously at a particular point of the process, before homogenization (See page 2, lines 32-35 and page 3, lines 1-2 of the present specification).

Yet, in a batch process like in BOYER, the sterol must be incorporated in the presence of a stabilizer and often an emulsifier to be carried out in an efficient and industrial way, in contrast to the claimed invention, wherein no stabilizer (referred to in the present specification as "thickener"), and no emulsifier are present.

In regard to the feature of the claimed invention that sterol and/or stanol are introduced into the milk base by continuous injection, it must be noted that the expression "continuous injection" designates not only a method consisting of

a mixing of two fluids, but also that the two fluids are initially conveyed in separate lines, and then mixed by joining these lines at a particular point of the method (before homogenization) and corresponds to an in-line injection.

Thus, the continuous injection is different from the batch used BOYER where raw materials are simply mixed at the beginning in a batch process.

In conclusion, the process of new claims 44-63, which correspond to claims 24-43, respectively, using neither a thickener nor an emulsifier, and being carried out by continuous injection and not by batch mixing, is unobvious over the proposed combination of DOAT and BOYER.

Therefore, withdrawal of the rejection is respectfully requested.

Claims 24-28 were rejected under 35 U.S.C. §103(a) as being unpatentable over DOAT U.S. 6,627,245 (DOAT). This rejection is respectfully traversed for the reasons that follow.

Independent claim 44 introduces sterol esters without thickeners and without emulsifiers.

In the process of DOAT, a suspension of water and thickeners is first prepared (see Col 4, lines 15-26) to obtain a solution with a viscosity of between 0.05 and 0.15 Pas. Then the phytosterols are added.



The position of the Official Action was that it would have been obvious to melt the phytosterols to permit efficient and repeatable injection of the phytosterols into the milk.

However, DOAT nevertheless requires thickeners. DOAT discloses in the same lines of Column 4 cited above: *"the structure created by the molecules of thickeners and the viscosity of the aqueous solution make it possible to keep the phytosterols particles in suspension with homogeneous diffusion"*.

Therefore, one skilled in the art would have been strongly discouraged from preparing a composition without the thickeners, as doing so would rendered the composition unsatisfactory for its intended purpose, i.e., keeping the phytosterols in suspension.

Therefore, new claims 44-48 are not rendered obvious by DOAT, and withdrawal of the rejection is respectfully requested.

### **Conclusion**

In view of the amendment to the claims and the foregoing remarks, this application is in condition for allowance at the time of the next Official Action. Allowance and passage to issue on that basis is respectfully requested.

Should there be any matters that need to be resolved in the present application, the Examiner is respectfully requested to contact the undersigned at the telephone number listed below.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

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